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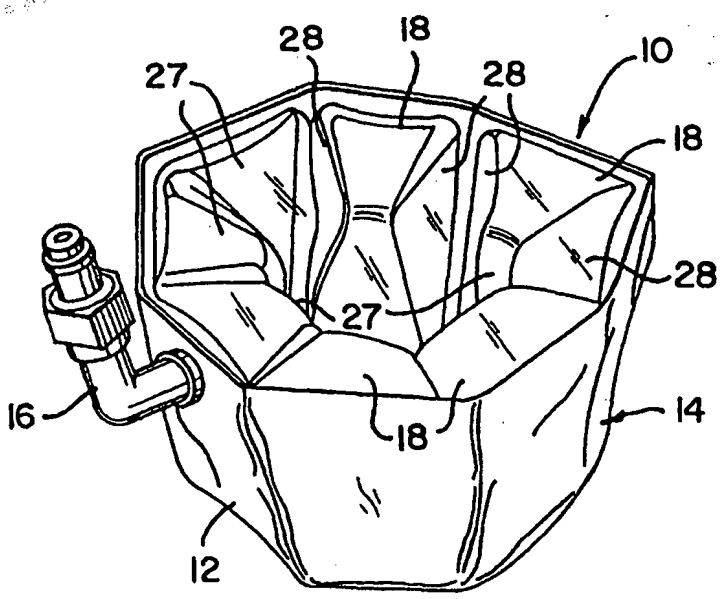
(54) Title: VENTRICULAR ASSIST DEVICE WITH PRE-FORMED INFLATION BLADDER

(57) Abstract

A ventricular assist device (10) is designed to assist a heart to pump blood by applying uniform pressure to a majority portion of an exterior ventricular surface of the heart. A specially configured bladder (14) is utilized to apply the pressure, and is prefabricated in an inflated, unfolded configuration to reduce wall stresses in the bladder when inflated. The inflatable bladder may also comprise a plurality of individually inflatable compartments (18). The compartments may have different dimensions to complement the dimensions of corresponding segments of the heart, and may be inflated at different times or at different pressures based upon the determined needs of the heart.



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VENTRICULAR ASSIST DEVICE WITH PRE-FORMED INFLATION BLADDER

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to temporary therapeutic devices to work in conjunction with a diseased or failing heart to satisfy the hemodynamic needs of a patient. More particularly, the invention relates to a ventricular assist device including a specially fabricated, inflatable bladder. The bladder minimizes wall stress in the bladder when it is inflated. The bladder may be designed with multiple independent, inflatable compartments to reduce the occurrence of pinch points in the bladder walls.

2. Discussion of the Related Art

The human heart is a very complicated organ that relies on both mechanical and electrical operation to properly perform. As with any complicated mechanism, problems can and do arise, and the heart is no exception. For example, over time the electrical pathways in the heart (which sequentially cause the atria and ventricles to contract) may fail, thereby causing the heart to lose its rhythm, which is known as arrhythmia. In that event, the ventricles will contract at improper times, and as a result the output of blood decreases. In addition, in some failing hearts the muscle of the heart no longer contracts the ventricles to a sufficient extent, also resulting in a dangerous reduction in the amount of blood flow.

Numerous attempts have been made to assist these diseased or failing hearts by applying external pressure directly to the heart. One such example is direct manual compression of the heart by a person's hand during open chest cardiopulmonary

resuscitation. Often, however, the patient requires cardiac or circulatory support for extended periods of time, such as hours, days, or even weeks, and it is quite difficult for medical personnel to apply a rhythmic pulsating pressure for such an extended period of time. Further, it is difficult if not impossible to apply by hand a uniform compressing force to a significant portion of the exterior ventricle surface of the chamber of the heart. Moreover, the chest should not be opened for extended periods of time because of the increased risk of infection. As such, manual manipulation of the heart is not a solution to the problem in most cases.

To overcome this problem, mechanical devices have been developed to apply external pressure directly to the heart. Some of these devices utilize an inflatable liner that surrounds the heart. For example, U.S. Patent No. 5,119,804 to Anstadt discloses a cup that is provided with an elastomeric liner. The heart is held in place within the liner, which is cyclically inflated and deflated to apply external pressure to the heart.

The prior art mechanical devices suffer from the shortcoming that they tend to apply pressure to the heart in a non-uniform manner. Such liners are typically made from a silicone rubber elastomer, which, when inflated, are inherently distended and assume an outwardly convex shape. As a result, those devices cause the heart to indent in its center portion, while allowing the heart ventricles to remain expanded at their upper and lower portions. Therefore, the prior art devices inefficiently assist in pumping blood to and from the heart.

Another shortcoming inherent in the prior art devices results from the fact that relatively high pressures are applied almost exclusively to the central portion of the ventricles' outer surfaces. This may eventually cause trauma (e.g., bruises) to the heart, especially if one of those devices is operated for an extended period of time.

Accordingly, it will be apparent that there continues to be a need for a ventricular assist device that intermittently applies pressure to the ventricles of the heart to assist the heart in pumping blood, and that is designed in such a way that it applies the

pressure to the heart in an efficient, safe manner. In addition, the need exists for a ventricular assist device with a relatively long useful life. The present invention addresses these needs.

SUMMARY OF THE INVENTION

Briefly, and in general terms, the present invention is directed to a ventricular assist device which includes a specially fabricated, inflatable bladder. During the fabrication process, the bladder is fabricated in an extended or inflated state in which it is substantially free of folds or creases. The ventricular assist device is then assembled and, when needed, extended over at least a portion of a patient's heart. In the deflated state, the bladder walls will likely be folded or creased, but when the bladder is inflated, it assumes the unfolded configuration in which it was fabricated. In this manner, stresses on the bladder material are minimized when the bladder is inflated, because there are substantially no folds or creases in the bladder when in the pressurized, inflated state.

Thus, in one illustrative embodiment the present invention is directed to an apparatus for assisting a heart to pump blood, comprising: an inflatable bladder configured to extend about at least a portion of the heart, the bladder being selectively inflatable to apply a compressive force to the portion of the heart, the bladder being fabricated to be substantially free of folds in an inflated state; and an inlet line connected for communication with the bladder, the inlet line being operative to selectively deliver pressurized fluid to, and withdraw pressurized fluid from, the bladder to alternately inflate and deflate the bladder.

In another illustrative embodiment, the present invention is directed to a method of creating an apparatus for assisting a heart to pump blood and of using the apparatus, comprising the steps of: fabricating an inflatable bladder in an inflated state to be substantially free of folds; connecting an inlet line to a port formed in the bladder, the inlet line being configured to engage a source of pressurized air and to deliver

pressurized air to the bladder to inflate the bladder; placing the bladder about at least a portion of a patient's heart; and selectively inflating and deflating the bladder, whereby the bladder is substantially free of folds when inflated.

In yet another illustrative embodiment, the present invention is directed to an inflatable bladder comprising plural individually inflated compartments. Each compartment can be separately controlled, and the dimensions of each compartment can be selected to complement the dimensions of a corresponding portion of a patient's heart. In this manner, the invention provides the ability for differential ventricular compression, and can match the dimensions of segments of the heart to optimize the application of force to the ventricles. Moreover, by providing plural discrete compartments, the invention reduces the likelihood of bladder pinch points and thereby increases the useful life of the device.

Thus, in one illustrative embodiment the present invention is directed to a system for assisting a heart to pump blood which comprises: a ventricular assist device configured to extend about at least a portion of the heart, the ventricular assist device being selectively inflatable to apply a compressive force to the portion of the heart, the ventricular assist device comprising plural inflatable compartments, each being independent from the others; and plural delivery conduits connected to the respective compartments and configured to engage respective sources of pressurized air to deliver pressurized air independently to each compartment.

In another illustrative embodiment, the present invention is directed to an apparatus for assisting a heart to pump blood, the apparatus comprising: an inflatable bladder configured to extend about at least a portion of the heart, the bladder being selectively inflatable to contract the portion of the heart, the bladder comprising at least two separate compartments, each being formed having predetermined dimensions to complement the dimensions of a respective portion of the heart; and at least two air lines connected to the respective compartments and configured to engage respective sources of pressurized air to deliver pressurized air independently to each of the compartments and

withdraw pressurized fluid from the compartments to alternately inflate and deflate the compartments.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and still further objects, features and advantages of the present invention will become apparent upon consideration of the following detailed description of specific embodiments thereof, especially when taken in conjunction with the accompanying drawings wherein:

Figure 1 is a perspective view of a ventricular assist device according to one illustrative embodiment of the present invention;

Figure 2 is a side view of plural inflatable compartments comprising a bladder incorporated in the ventricular assist device of Fig. 1;

Figure 3 is a side view taken along the line 3-3 of Fig. 2 and looking in the direction of the arrows;

Figure 4 is a top plan view taken along the line 4-4 of Fig. 2 and looking in the direction of the arrows;

Figure 5 is a perspective view of a second illustrative embodiment of the ventricular assist device of the present invention;

Figure 6 is a perspective view of another illustrative embodiment of the ventricular assist device of the present invention;

Figure 7 is a top plan view of the ventricular assist device of the present invention with the bladder in a deflated state;

Figure 8 is a top plan view similar to Fig. 7 and showing the bladder in an inflated state;

Figure 9 is a perspective view of a ventricular assist device according to another illustrative embodiment of the present invention;

Figure 10 is a top plan view of the ventricular assist device of the present invention with the bladder in a deflated state;

Figure 11 is a perspective view of another illustrative embodiment of the ventricular assist device of the present invention;

Figure 12 is a top plan view similar to Fig. 10 and showing the bladder in an inflated state;

Figure 13 is a side view of a ventricular assist device with compartments of predetermined dimensions to complement corresponding segments of the heart; and

Figure 14 is a cross-sectional view taken along the line 14-14 of Fig. 13 and looking in the direction of the arrows.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to Figs. 1 and 2, a ventricular assist device 10 according to one illustrative embodiment of the present invention is shown. The ventricular assist device 10 is preferably controlled in such a manner that it is inflated and deflated at a predetermined and controllable rate in concert with the patient's heart beat, and in particular with the contraction of the ventricles of the heart. The ventricular assist device includes a specially fabricated bladder 14 that is inflated and deflated at controlled rates so that the bladder selectively compresses directly against at least a portion of the ventricles and thereby assists in compressing the ventricles to pump blood through the patient's circulatory system. According to the present invention, the bladder is fabricated, for example by a thermoforming process, in an extended (or inflated), unfolded configuration to define the inflated state of the bladder. Thus, in use, when the bladder is inflated, it resumes the outwardly extended configuration in which it was fabricated, and is at least substantially free of folds or creases. Conversely, when the bladder is deflated, folds and/or creases may appear in the bladder. In this manner, wall stresses in the bladder are minimized, leading to an extended useful life of the device. In addition, the device is relatively easy to manufacture and assemble.

The ventricular assist device 10 of the present invention may take many different forms. In one illustrative embodiment, the ventricular assist device is generally

cylindrical in shape and is designed for slidable extension over the human heart, more specifically over at least a portion of the ventricles of the heart. As shown in Figs. 1 and 2, the ventricular assist device 10 in one illustrative embodiment generally comprises a cylindrical outer wall 12, plural flexible compartments 18 which define the inflatable bladder 14 and are disposed radially inwardly of the outer wall, and one or more tubes 16 which are in fluid communication with the respective compartments of the bladder to selectively deliver pressurized fluid to, and withdraw pressurized fluid from, compartments 18.

The outer wall 12 defines the back or rear of the bladder 14 and cooperates with the bladder to seal off the compartments and define the plural hermetically sealed compartments. The outer wall is preferably made from a substantially non-stretchable, yet foldable and bendable material so that it may easily conform to the outer shape of a heart. In one illustrative embodiment, the outer wall is made from a combination of biocompatible, reinforced and non-reinforced polyurethane, or other elastic polymers. In one embodiment the polyurethane defines a fluid impermeable layer that is reinforced with a non-stretchable reinforcing layer, for example, a polyester weave. The outer wall 12 is preferably thicker, stiffer, or of a higher durometer than the walls of the compartments 18 comprising the bladder 14, or incorporates other mechanical means, such as reinforcing members, to resist radial outward expansion of the outer wall when the bladder is inflated.

The outer wall is further formed with one or more openings (not shown) that are in fluid communication with first ends of the respective tubes 16. The respective second ends of the tubes are connected to one or more sources of pressurized fluid (not shown) to selectively inflate the bladder. In the illustrative embodiment shown, when the bladder is deflated, the compartment walls fold in upon themselves while remaining in relatively close proximity to the heart (FIG. 7). Then, as the bladder is inflated, the compartment walls at least substantially unfold as they are driven radially inwardly to assume their pre-fabricated, extended configurations and uniformly engage

the portion of the heart that is contained within the ventricular assist device 10 (FIG. 8).

The dimensions of the ventricular assist device 10, and more particularly of the bladder 14, are determined, at least in part, based on the size of the heart to be assisted. It will be apparent to those skilled in the art that different sizes of bladders may be designed to accommodate patients with different sized hearts, as is described in greater detail in U.S. Provisional Patent Application Serial Number 60/098,130, filed August 27, 1998, and entitled "METHOD AND APPARATUS FOR ASSISTING A HEART TO PUMP BLOOD" and U.S. Non-Provisional Application Serial Number 09/185,287, filed on November 11, 1998, entitled "METHOD AND APPARATUS FOR ASSISTING A HEART TO PUMP BLOOD", the disclosures of which are incorporated herein by reference as if set forth herein in its entirety.

Referring now to FIG. 2, there is shown one illustrative embodiment of the bladder 14 incorporated in the ventricular assist device 10. The bladder 14 preferably comprises plural compartments 18, each of which is fabricated in an inflated, unfolded configuration. The compartments are preferably formed of a semi-compliant elastomer, for example a combination of biocompatible, reinforced and non-reinforced polyurethane, or other suitable elastic polymer. The respective compartments are preferably fabricated by a thermoforming process, which, as is well known to those skilled in the art, is essentially a solid-phase deformation process. Preferably, a sheet of suitable polymer is heated and then formed into the desired shape in a suitable mold. The sheet is heated until it begins to melt, is draped over the mold, and a vacuum is used to remove any air from around the mold, such that the heated sheet takes the shape of the mold and then cools to take the shape. Alternative methods may be used to form the compartments, such as solid-phase pressure forming and the like.

By fabricating the compartments 18 in the inflated position, wall stresses in the inflated portion of the compartments are minimized when the bladder is inflated. This is due to the fact that the compartments' walls are substantially free of folds or creases when they are inflated. This results in a number of significant benefits, one of

which being that the device is relatively easy to manufacture with the compartments in the inflated configurations. In addition, the useful life of the device is extended, because the wall stresses in the bladder walls are minimized. Furthermore, the efficiency of the device is increased, because the pressure is applied uniformly over the ventricles of the heart.

The compartments 18 may have many different cross-sectional shapes. In one illustrative embodiment, each of the compartments is generally D-shaped in vertical cross-section (FIG. 3), and generally V-shaped in horizontal cross-section (FIG. 4). Because the heart is generally conical, the compartments are preferably wider in cross-section at the lower end than at the upper end. In other words, the lower ends of the compartments project radially inwardly farther than do the upper ends, to complement the shape of the ventricles of the heart, and to thereby apply a more uniform pressure to the entire portion of the ventricle contained within the ventricular assist device. Thus, the compartments 18 comprise generally planar contact surfaces 27 which extend axially and radially inwardly at a preselected angle with respect to a longitudinal axis 29 defined by the device 10. The orientation of the contact surfaces complements the generally conical shape of the lower portion of the ventricles. In addition, the compartments comprise angled side walls 28 which taper as they extend radially inwardly to define the V-shaped compartments.

The compartments 18 are preferably spaced predetermined distances apart and mounted to the outer wall 12 by means of a UV adhesive, cyanoacrylate, heat sealing, or other suitable means.. The spaced positioning of the compartments, coupled with the V-shaped cross-section of each compartment, allows the bladder to assume a circular configuration (FIGS. 7 and 8). Thus, the compartments cooperate to define a generally annular, angled interface for contacting a substantial portion of the ventricles of the heart.

While the bladder 14 is shown and described as comprising plural individual compartments 18, it will be apparent that the bladder may alternatively

comprise a single, elongated compartment fabricated in the inflated, extended configuration, and which is mounted on the outer wall 12 and formed into a cylindrical configuration. Thus, the present invention is not limited to multiple compartment designs.

Referring now to Figs. 5 and 6, the specially configured bladder 14 may be incorporated into various types of ventricular assist devices, of which the devices shown in FIGS. 5 and 6 are merely two examples. Each device is described in greater detail in the above-mentioned U.S. Provisional Patent Application Serial Number 60/098,130 and in Non-Provisional Patent Application Serial Number 09/185,287. The ventricular assist device 100 shown in Fig. 5 includes plural tubes 102 connected to the bladder 14 at spaced apart locations. The tubes are connected to one or more sources of pressurized fluid (not shown) to supply pressurized fluid to the respective compartments 18. A vacuum tube 104 is in fluid communication with the interior of the device 100, and is connectable to a vacuum source to create a vacuum inside the device in order to draw the device into engagement with the patient's heart.

Figure 6 shows yet another ventricular assist device 110 with which the bladder 14 is suitable for use. Briefly, the ventricular assist device 110 is in the form of an upwardly opening receptacle defining an interior chamber 112 sized for making a relatively close fit about at least a portion of a patient's heart. The chamber is defined by an annular inflatable bladder 114 and an upwardly opening suction membrane 116 disposed inwardly of the bladder and connected to the bladder. The suction membrane is responsive to the application of negative pressure inside the device 110 to be drawn radially inwardly and into engagement with the heart.

The ventricular cuff 110 further includes a flexible, cleated finger assembly 118 for releasably engaging the outer surface of the heart (Fig. 6) and an apical reinforcing support assembly including a spatula 120, a backplate reinforcement 122, and a pair of supporting rods 124, all of which are described in greater detail in U.S. Provisional Patent Application Serial Number 60/098,130 and in Non-Provisional

Application Serial Number 08/185,287.

Alternatively, the ventricular assist device 10 may be in the form of an elongated strip of flexible material with plural compartments 18 mounted thereon at spaced locations along the length of the strip, and with complementary fasteners at either end of the strip. In use, the bladder may be wrapped around a patient's heart, and the fasteners engaged together to secure the bladder in place encasing or encircling the ventricles of the heart. A form of such device is disclosed in the above-mentioned U.S. Provisional Patent Application Serial Number 60/098,130 and in Non-Provisional Application Serial Number 09/185,287.

In use, the ventricular assist device 10 is positioned around or over at least a portion of the patient's heart, either by wrapping the device around the heart or sliding the device over the heart. In at least one embodiment, a vacuum source (not shown) is then fluidly connected to the vacuum tube 104, and a negative pressure is created inside of the device 10, which draws the ventricular assist device into secure engagement with the ventricular heart tissue. Alternately, the device may be wrapped about the heart and secured thereto by a fastener, suture, or other suitable means in a manner known to those skilled in the art. An intermittent fluid pressure is then alternately delivered and withdrawn through the respective tubes 16 to cyclically inflate and deflate the compartments of the bladder 14.

During the deflation stage, it is desirable to quickly reduce the air pressure within the compartments to prevent the ventricular assist device 10 from interfering with the refilling of the ventricles of the heart. Thus, during the deflation stage, the source of pressurized fluid is preferably operative to actively withdraw the fluid from the compartments 18. Then, as the ventricles re-fill with blood, they expand. This ventricular expansion displaces the compartment walls of the bladder 14 radially outwardly toward the outer wall 12, such that the compartment walls have folds or creases 32 (FIG. 7). Conversely, when the compartments are inflated, the compartments assume their respective pre-fabricated, substantially unfolded configurations to apply a

uniform pressure across the portion of the ventricles of the heart which are inside the device 10 (FIG. 8). Because the bladder preferably does not stretch beyond its pre-fabricated shape, the heart is not contorted into a generally hourglass shape when the bladder is inflated and comes into contact with the heart.

The pressure fluid supplied to and removed from tubes 16 is preferably a pneumatic fluid, such as, for example, air, carbon dioxide or an inert gas (e.g., argon). Alternatively, the pressure fluid may be a hydraulic fluid, such as, for example, water or saline.

Referring now to Fig. 9, a ventricular assist device 100 according to one illustrative embodiment of the present invention is shown. The ventricular assist device 200 is preferably controlled in such a manner that it is inflated and deflated at a predetermined, controllable rate in concert with the patient's heart beat, and in particular with the contraction of the ventricles of the heart. The ventricular assist device includes an inflatable bladder 214 that is inflated and deflated at controlled rates so that the bladder selectively compresses directly against at least a portion of the ventricles and thereby assists in compressing the ventricles to pump blood through the patient's circulatory system. According to the present invention, the bladder comprises a plurality of discrete, individually inflated compartments 216 connected to respective air conduits 218. Thus, the compartments may be inflated at different rates and/or at different pressure levels. In addition, by providing plural separate compartments rather than a single annular bladder, the occurrence of bladder pinch points is substantially reduced, leading to an extended useful life of the device, as is described in greater detail below.

The ventricular assist device 200 of the present invention may take many different forms. In one illustrative embodiment, the ventricular assist device is generally cylindrical in shape and is designed for slidable extension over the human heart, more specifically over at least a portion of the ventricles of the heart. As shown in Fig. 9, the ventricular assist device 200 in one illustrative embodiment generally comprises a

cylindrical outer wall 212, the plural flexible compartments 216 which define the inflatable bladder 214 and which are disposed radially inwardly of the outer wall, and a plurality of air conduits 218, each of which is in fluid communication with a respective one of the bladder compartments to selectively deliver pressurized fluid to, and withdraw pressurized fluid from, the corresponding compartment.

The outer wall 212 defines the back or rear of the bladder 214 and cooperates with the bladder to seal off each of the compartments and define the plural hermetically sealed, individually inflatable compartments 216. The outer wall is preferably made from a substantially non-stretchable, yet foldable and bendable material so that it may easily conform to the outer shape of a heart. In one illustrative embodiment, the outer wall is made from a combination of biocompatible, reinforced and non-reinforced polyurethane, or other elastic polymers. In one embodiment the polyurethane defines a fluid impermeable layer that is reinforced with a non-stretchable reinforcing layer, for example, a polyester weave. The outer wall 212 is preferably thicker, stiffer, or of a higher durometer than the walls of the compartments 216 comprising the bladder 214, or incorporates other mechanical means, such as reinforcing members, to resist radial outward expansion of the outer wall when the bladder is inflated.

The outer wall is further formed with one or more openings 219 (Fig. 9) that are in fluid communication with first ends of the respective conduits 218. The respective second ends of the conduits are connected to one or more sources of pressurized fluid (not shown) to selectively inflate the corresponding compartments of the bladder.

The dimensions of the ventricular assist device 200, and more particularly of the bladder 214, are determined, at least in part, based on the size of the heart to be assisted. It will be apparent to those skilled in the art that different sizes of bladders may be designed to accommodate patients with different sized hearts, as is described in greater detail in U.S. Provisional Patent Application Serial Number 60/098,130, and in

U.S. Non-Provisional Application Serial Number 09/185,287.

Because the heart is asymmetric, each of the compartments 216 is preferably formed with unique dimensions to complement a corresponding portion of the heart's surface. For example, Figs. 13 and 14 show an alternative embodiment of the compartments 216, in which the compartments are generally hemispherical in horizontal cross-section (Fig. 14). In that embodiment, the compartments are preferably formed with relatively large radii R (Fig. 14) to reduce edge effects during inflation. Moreover, because the right ventricle and left ventricle are typically not the same size, the compartment 216' (which will be aligned with the right ventricle) is preferably formed with dimensions complementing those of the right ventricle, while the compartment 216" (which will be aligned with the left ventricle) is preferably formed with different dimensions complementing those of the left ventricle. In this manner, the bladder 214 of the present invention provides better coverage of the ventricles than does a device with an annular bladder that, by design, cannot be sized to complement the dimensions of both the left and right ventricles. In the embodiment of Fig. 13, the device 210 can be formed with indicia (not shown) on the outer wall 212 to assist a clinician to properly align the device 210 with the heart before extending the device over the heart.

The bladder 214 may comprise of two compartments 216, three compartments, or more. It has been found that as the number of compartments increases, the occurrence of pinch points decreases. Thus, it is preferred to provide a relatively large number of individual compartments which are spaced apart around the device 210.

It has been found that a bladder comprising a single, annular inflatable compartment tends to experience a large occurrence of pinch points when the bladder is inflated. When the bladder is deflated, folds or creases appear in the bladder wall. As the bladder inflates, some of the folds remain, and as the high pressure is established inside the bladder, pinch points are created. This tends to fatigue the bladder wall, thereby reducing the useful life of the device. Thus, the present invention, by providing

multiple compartments 216, at least substantially reduces the occurrence of pinch points in the device 210, thereby increasing the useful life of the device.

Referring now to Fig. 11, the compartmentalized bladder 214 may be incorporated into various types of ventricular assist devices, of which the devices shown in Figs. 11 are merely two examples, in addition to the example shown in Fig. 9. Each of the devices in Figs. 5 and 11 is described in greater detail in the above-mentioned U.S. Provisional Patent Application Serial Number 60/498,130 and in U.S. Non-Provisional Application Serial Number 09/185,287.

Figure 11 shows ventricular assist device 210 with which the bladders 214 is suitable for use. Briefly, the ventricular assist device 210 is in the form of an upwardly opening receptacle defining an interior chamber 212 sized for making a relatively close fit about at least a portion of a patient's heart. The chamber is defined by an annular inflatable bladder 214 and an upwardly opening suction membrane 216 disposed inwardly of the bladder and connected to the bladder. The suction membrane is responsive to the application of negative pressure inside the device 210 to be drawn radially inwardly and into engagement with the heart.

The ventricular cuff 210 further includes a flexible, cleated finger assembly 218 for releasably engaging the outer surface of the heart (Fig. 11) and an apical reinforcing support assembly including a spatula 220, a backplate reinforcement 222, and a pair of supporting rods 224, all of which are described in greater detail in U.S. Provisional Patent Application Serial Number 60/098,130 and in U.S. Non-Provisional Application Serial Number 09/185,287.

As described above, the compartments 216 can be formed with different dimensions to complement the dimensions of different areas of the heart, such that when the device 210 is in place, the compartments align with the corresponding segments of the heart to provide optimal ventricle coverage.

An intermittent fluid pressure is then alternately delivered and withdrawn through the respective conduits 218 to the respective compartments 216 to cyclically

inflate and deflate the compartments of the bladder 214. Because each compartment is driven by a separate conduit 218, each compartment can be controlled separately. Thus, one compartment can be inflated while others remain deflated (e.g. if only one ventricle requires assistance), or one compartment can be inflated to a particular pressure level while the others are inflated to different pressure levels (e.g., where one ventricle requires more assistance than the other). Of course, each compartment can also be inflated at the same time, and to the same pressure level. Thus, the present invention provides a clinician with a number of options so that he or she can optimize the assistance of a patient's heart.

During the deflation stage, it is desirable to quickly reduce the air pressure within the compartments to prevent the ventricular assist device 210 from interfering with the refilling of the ventricles of the heart. Thus, during the deflation stage, the source(s) of pressurized fluid are preferably operative to actively withdraw the fluid from the respective compartments 216. Then, as the ventricles re-fill with blood, they expand. This ventricular expansion displaces the compartment walls of the bladder 214 radially outwardly toward the outer wall 212, to allow the ventricles to fill with blood. When the source(s) subsequently inflate the compartments, the compartments apply a uniform pressure across the portion of the ventricles of the heart which are inside the device 210 and aligned with the respective compartments (Fig. 11). Because the bladder preferably does not stretch beyond its pre-fabricated shape, the heart is not contorted into a generally hourglass shape when the bladder is inflated and comes into contact with the heart.

From the foregoing, it will be apparent that the ventricular assist device of the present invention provides an efficient, reliable device for assisting a malfunctioning heart to pump blood by applying a substantially uniform, intermittent pressure to the ventricle outer walls. Moreover, by providing the specially configured bladder, the stresses which would otherwise exist in the bladder wall are minimized, if not substantially eliminated.

While the invention has been particularly shown and described with reference to illustrative embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

WE CLAIM:

1. An apparatus for assisting a heart to pump blood, the apparatus comprising:

an inflatable bladder configured to extend about at least a portion of the heart, the bladder being selectively inflatable to apply a compressive force to the portion of the heart, the bladder being fabricated in an extended configuration which is substantially free of folds; and

an inlet line connected for communication with the bladder, the inlet line being operative to selectively deliver pressurized fluid to, and withdraw pressurized fluid from, the bladder to alternately inflate and deflate the bladder, whereby in an inflated state, the bladder resumes the extended configuration in which it is at least substantially free of folds.

2. The apparatus of claim 1 further including a suction membrane configured to make a close fit about at least a portion of the heart, and a suction line in communication with an interior chamber of the suction membrane, the suction line being operative to create a vacuum in the chamber to draw the suction membrane inwardly into engagement with the heart.

3. The apparatus of claim 2, wherein the bladder and suction membrane are connected together adjacent the respective upper ends of the bladder and suction membrane.

4. The apparatus of claim 1 further comprising at least one resilient reinforcing finger disposed inwardly of the suction membrane, the reinforcing finger including plural cleats to releasably engage the heart when the suction line is operative.

5. The apparatus of claim 1, wherein the bladder comprises plural inflatable compartments.

6. The apparatus of claim 5, wherein each of the compartments is generally D-shaped in cross-section when inflated.

7. The apparatus of claim 1, wherein the bladder includes an outer wall and an inner wall, the outer wall being reinforced to resist radially outward expansion during inflation of the bladder.

8. The apparatus of claim 5 further comprising plural inlet lines in communication with the respective compartments.

9. The apparatus of claim 1 further comprising plural inlet lines, each of which is in fluid communication with the bladder at respective spaced apart locations along the bladder.

10. The apparatus of claim 1, wherein the bladder is in the form of an elongated strip including first and second ends, the bladder being formed of a flexible material to be wrapped about the heart, the bladder further including a fastener device to secure the bladder in place about the heart.

11. An apparatus for assisting a heart to pump blood, the apparatus comprising:

an inflatable bladder configured to extend about at least a portion of the heart, the bladder being selectively inflatable to contract the portion of the heart, the bladder comprising a plurality of individual compartments with a pre-fabricated, inflated configuration which is substantially free of folds, such that when the bladder is inflated,

the compartments are at least substantially free of folds; and

an inlet line connected for communication with the bladder, the inlet line being operative to selectively deliver pressurized fluid to and withdraw pressurized fluid from the bladder to alternately inflate and deflate the compartments of the bladder.

12. The apparatus of claim 11, further including a suction membrane configured to make a close fit about at least a portion of the heart, and a suction line in communication with an interior chamber of the suction membrane, the suction line being operative to create a vacuum in the chamber to draw the suction membrane inwardly into engagement with the heart.

13. The apparatus of claim 12, wherein the bladder and suction membrane are connected together adjacent the respective upper ends of the bladder and suction membrane.

14. The apparatus of claim 11, further comprising at least one resilient reinforcing finger disposed inwardly of the suction membrane, the reinforcing finger including plural cleats to releasably engage the heart when the suction line is operative.

15. The apparatus of claim 11, wherein the bladder comprises plural inflatable compartments.

16. The apparatus of claim 15, wherein each of the compartments is generally D-shaped in cross-section when inflated.

17. The apparatus of claim 11, wherein the bladder includes an outer wall and an inner wall, the outer wall being reinforced to resist radially outward expansion during inflation of the bladder.

18. The apparatus of claim 15 further comprising plural inlet lines in communication with the respective compartments.

19. The apparatus of claim 11 further comprising plural inlet lines, each of which is in fluid communication with the bladder at respective spaced apart locations along the bladder.

20. The apparatus of claim 11, wherein the bladder is in the form of an elongated strip including first and second ends, the bladder being formed of a flexible material to be wrapped about the heart, the bladder further including a fastener device to secure the bladder in place about the heart.

21. A method of creating an apparatus for assisting a heart to pump blood and of using said apparatus, comprising the steps of:

fabricating an inflatable bladder with a pre-fabricated, inflated configuration which is at least substantially free of folds;

connecting an inlet line to a port formed in the bladder, the inlet line being configured to engage a source of pressurized fluid and to deliver pressurized fluid to the bladder to inflate the bladder;

placing the bladder about at least a portion of a patient's heart; and

selectively inflating and deflating the bladder, whereby the bladder is substantially free of folds when inflated.

22. The method of claim 21, wherein the step of fabricating the inflatable bladder comprises fabricating the bladder by a thermoforming process.

23. The method of claim 21, wherein the step of fabricating the inflatable bladder comprises fabricating a plurality of compartments, each being fabricated in an inflated, substantially unfolded state.

24. A system for assisting a heart to pump blood, the system comprising:

a ventricular assist device configured to extend about at least a portion of the heart, the ventricular assist device including a bladder that is selectively inflatable to apply a compressive force to the portion of the heart, the ventricular assist device comprising plural inflatable compartments, each being independent from the others; and

plural delivery conduits connected to the respective compartments and configured to engage respective sources of pressurized air to deliver pressurized air independently to each compartment.

25. The apparatus of claim 24, further including a suction membrane configured to make a close fit about at least a portion of the heart, and a suction line in communication with an interior chamber of the suction membrane, the suction line being operative to create a vacuum in the chamber to draw the suction membrane inwardly into engagement with the heart, and wherein the compartments and suction membrane are connected together.

26. The apparatus of claim 25, wherein the compartments and suction membrane are connected together adjacent the respective upper ends of the compartment and suction membrane.

27. The apparatus of claim 24, wherein the sources of pressurized air comprise a single device with plural independent outputs.

28. The apparatus of claim 24, wherein the bladder includes an outer wall and an inner wall, the outer wall being reinforced to resist radially outward expansion during inflation of the bladder.

29. The apparatus of claim 24, wherein the ventricular assist device is in the form of an elongated strip including first and second ends, the ventricular assist device being formed of a flexible material to be wrapped about the heart, and further including a fastener device to secure the ventricular assist device in place about the heart.

30. An apparatus for assisting a heart to pump blood, the apparatus comprising:

an inflatable bladder configured to extend about at least a portion of the heart, the bladder being selectively inflatable to contract the portion of the heart, the bladder comprising at least two separate compartments, each being formed having predetermined dimensions to complement the dimensions of a respective portion of the heart; and

at least two fluid conduits connected to the respective compartments and configured to engage respective sources of pressurized air to deliver pressurized air independently to each of the compartments and withdraw pressurized fluid from the compartments to alternately inflate and deflate the compartments.

31. The apparatus of claim 30, further including a suction membrane configured to make a close fit about at least a portion of the heart, and a suction line in communication with an interior chamber of the suction membrane, the suction line being operative to create a vacuum in the chamber to draw the suction membrane inwardly into engagement with the heart, and wherein the bladder and suction membrane are connected together.

32. The apparatus of claim 31, wherein the bladder and suction membrane are connected together adjacent the respective upper ends of the bladder and suction membrane.

33. The apparatus of claim 30, further comprising at least one resilient reinforcing finger disposed inwardly of the suction membrane, the reinforcing finger including plural cleats to releasably engage the heart when the suction line is operative.

34. The apparatus of claim 30, wherein each of the compartments is generally D-shaped in cross-section when inflated.

35. The apparatus of claim 30, wherein the bladder includes an outer wall and an inner wall, the outer wall being reinforced to resist radially outward expansion during inflation of the bladder.

36. The apparatus of claim 30, wherein the bladder is in the form of an elongated strip including first and second ends, the bladder being formed of a flexible material to be wrapped about the heart, the bladder further including a fastener device to secure the bladder in place about the heart.

37. The apparatus of claim 30, wherein one of the compartments is sized to complement at least a portion of the right ventricle of the patient's heart, and another of the compartments is sized to complement at least a portion of the left ventricle of the patient's heart.

38. A method of assisting a heart to pump blood, comprising:

placing a bladder about the periphery of the heart, the bladder comprising at least two inflatable compartments at spaced apart locations;

connecting the at least two compartments to respective sources of pressurized air; and

operating the sources of pressurized air to independently inflate the respective compartments.

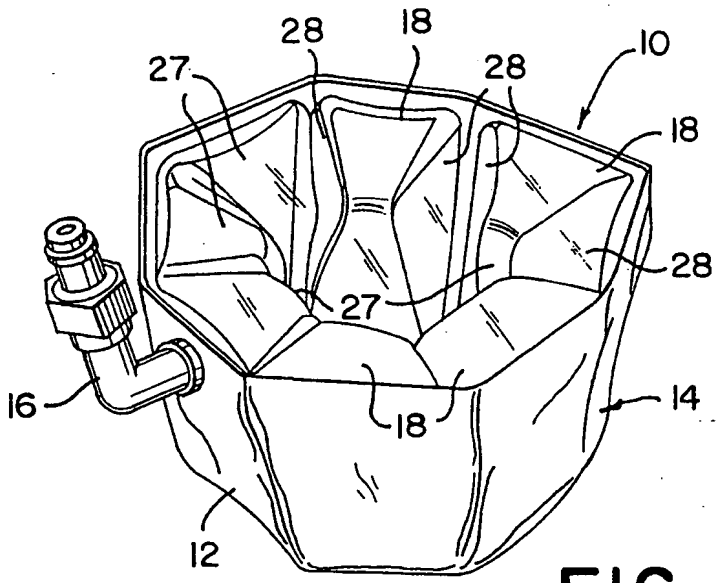
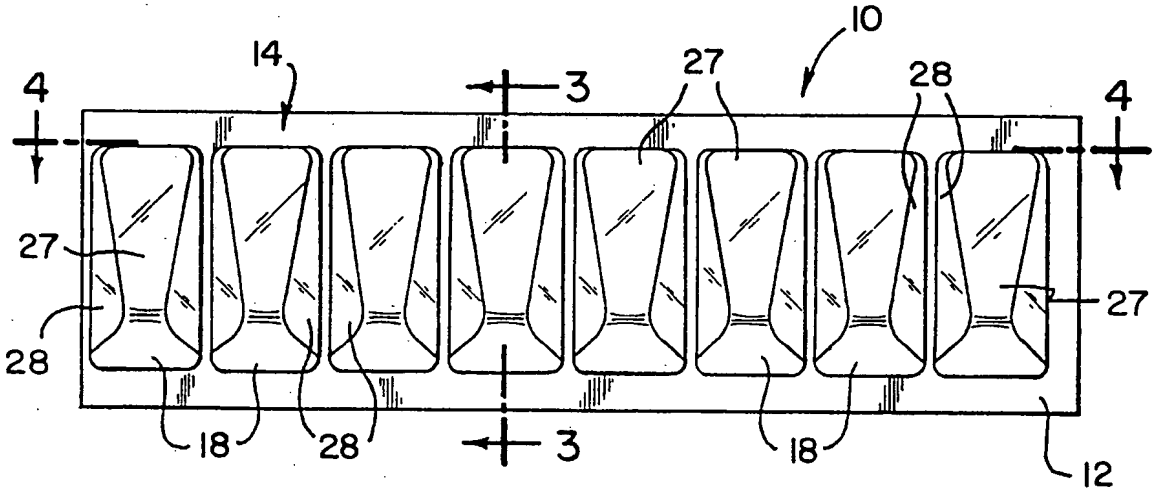


FIG. 1

FIG. 2



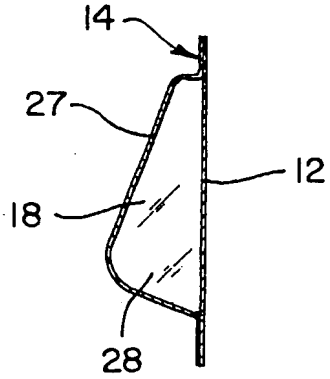
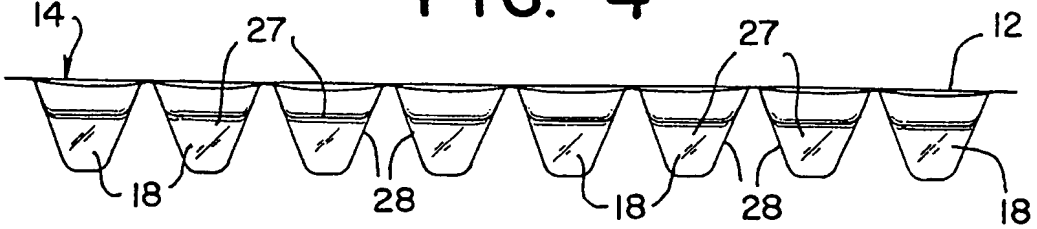


FIG. 3

FIG. 4



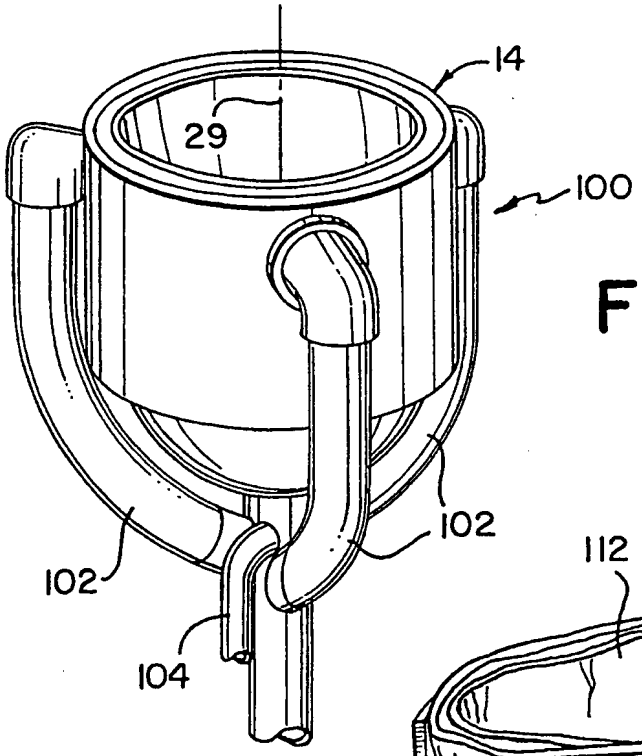


FIG. 5

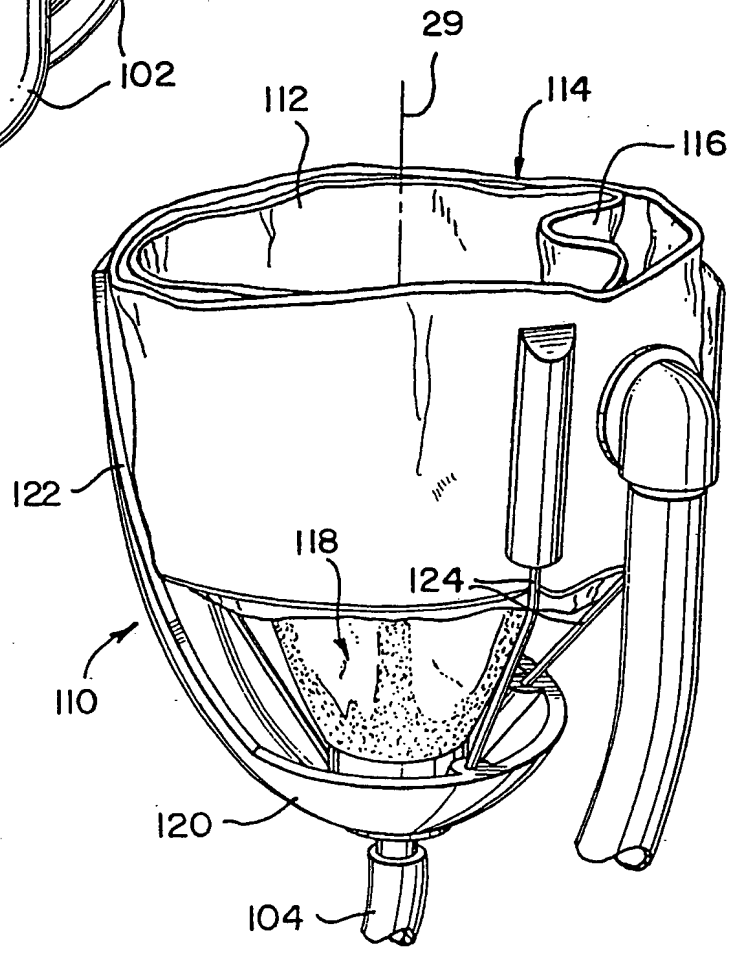


FIG. 6

FIG. 7

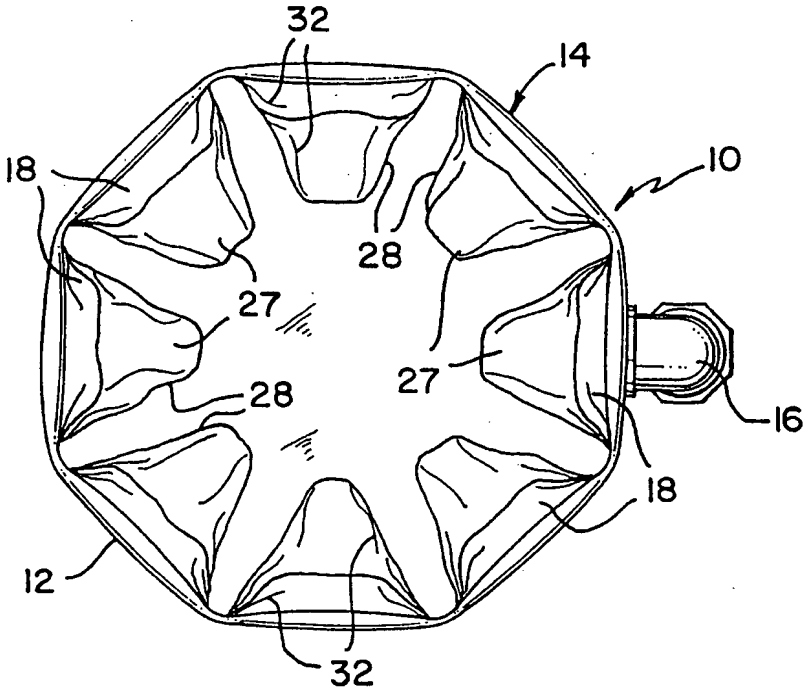
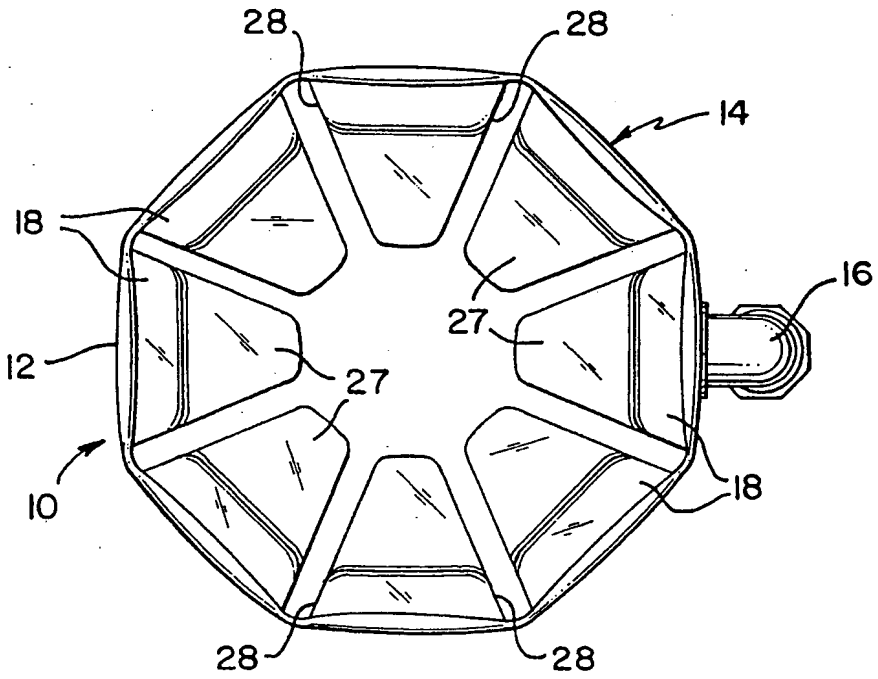


FIG. 8



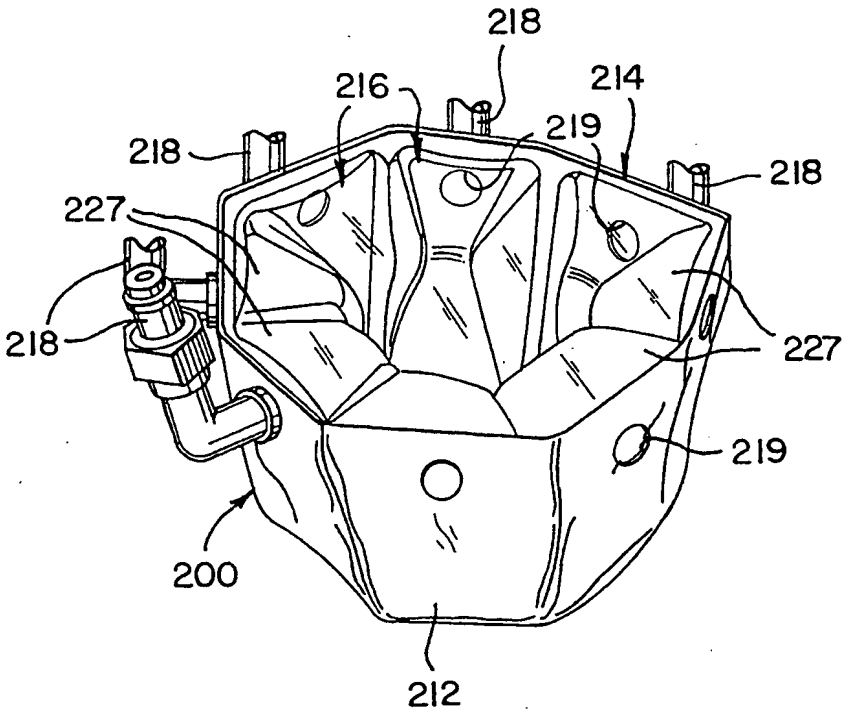

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FIG. 9

FIG. 10

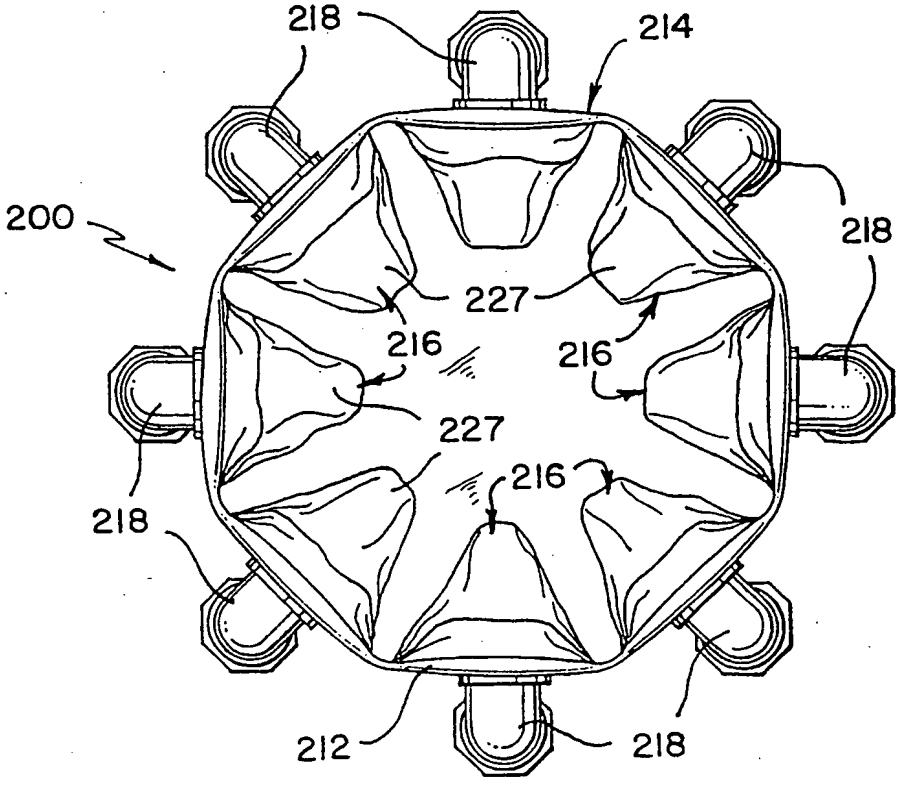
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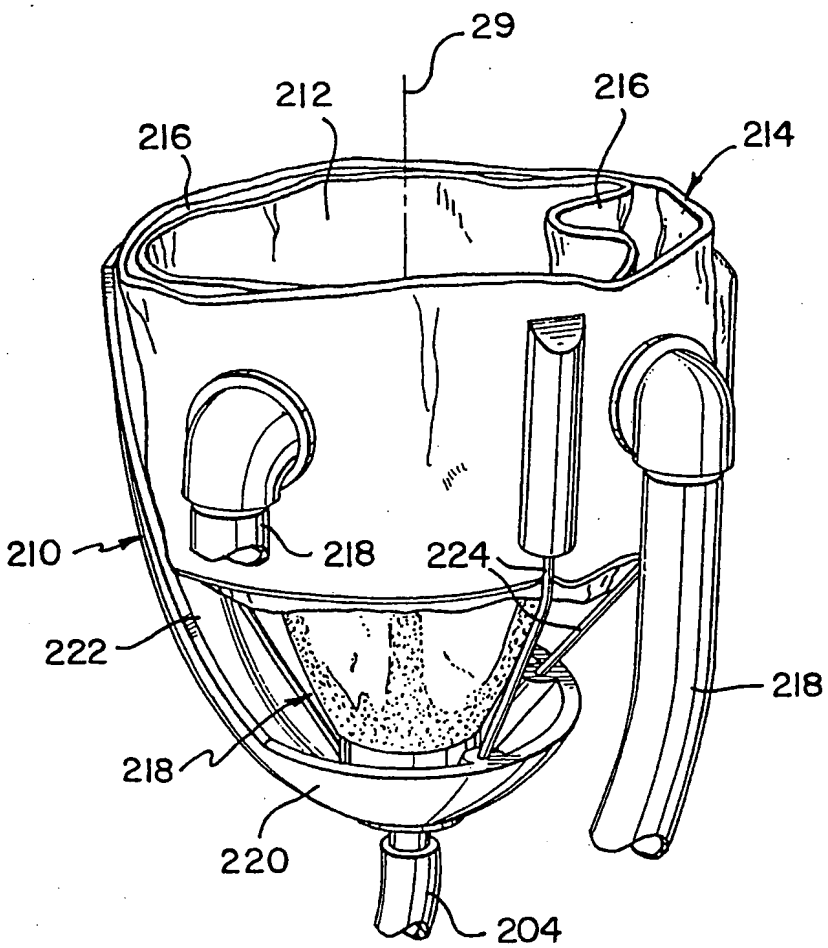
FIG. 11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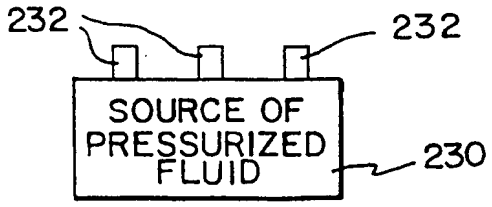
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SOURCE OF PRESSURIZED FLUID
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FIG. 12

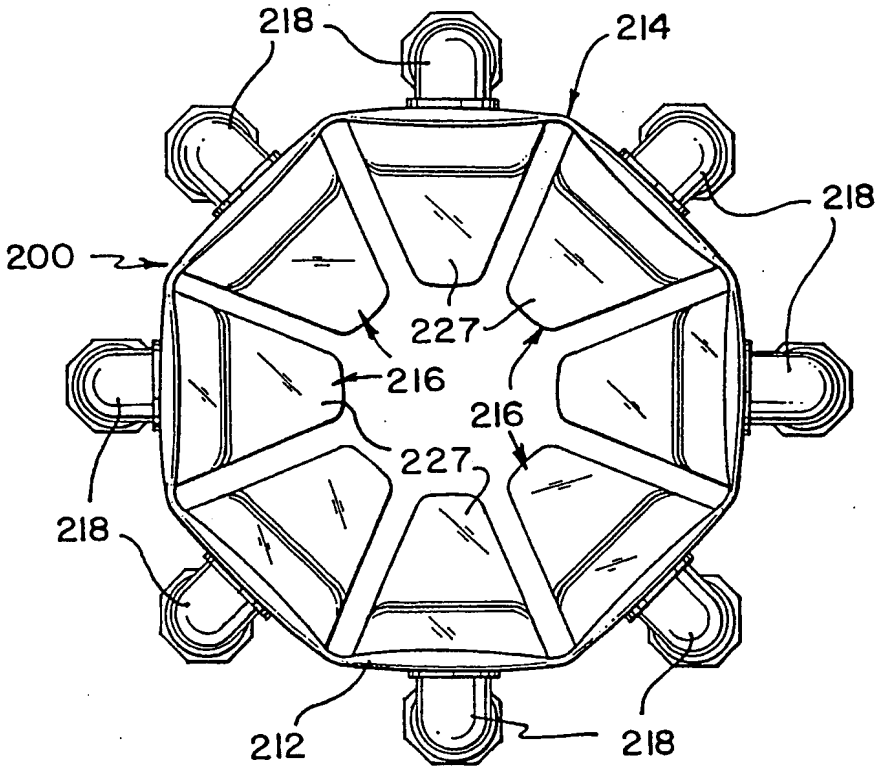


FIG. 13

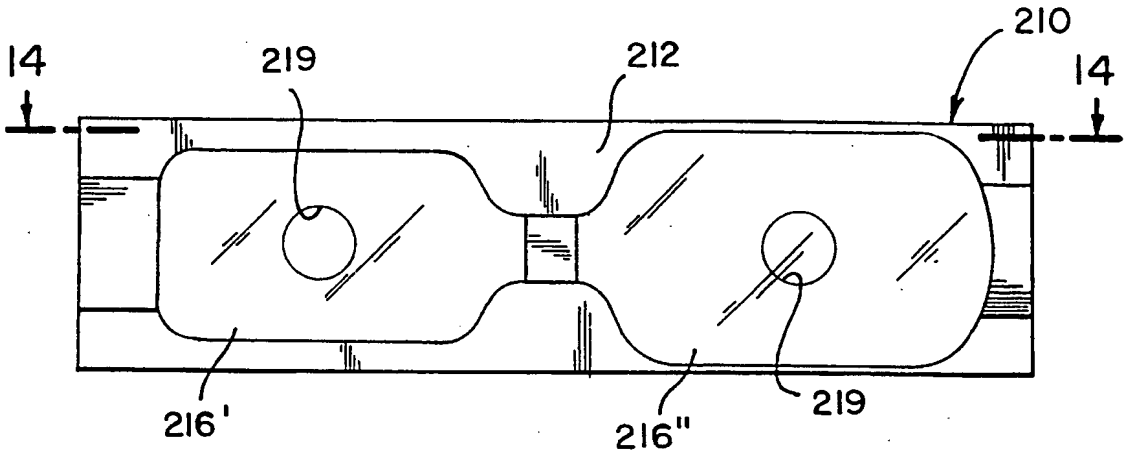
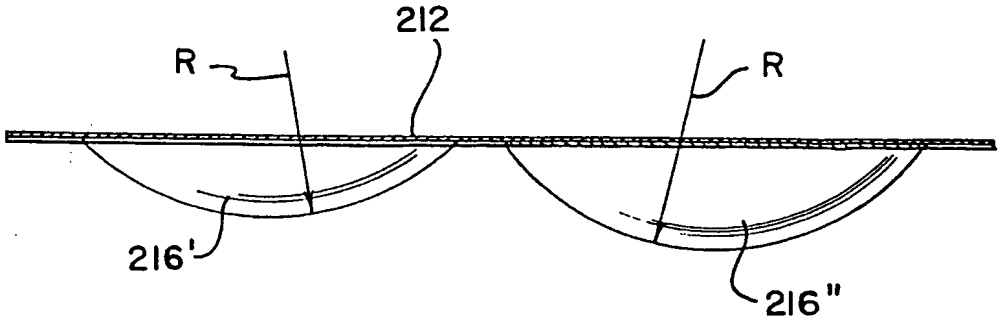


FIG. 14



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/26042

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 1/10
US CL :600/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/16-18; 623/3

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 3,613,672 A (SCHIFF) 19 October 1971, entire document.	1, 7, 21 --- 22
X --- Y	US 5,169,381 A (SNYDERS) 08 Decmeber 1992, entire document.	21, 24, 27, 30, 34, 37, 38 --- 22

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

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Date of the actual completion of the international search	Date of mailing of the international search report
09 FEBRUARY 2000	08 MAR 2000
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